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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/519,677 | 01/07/2005 | Akira Yanagawa | 264232US0PCT | 9965 |

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| EXAMINER | |
|---|---|
| ALSTRUM ACEVEDO, JAMES HENRY | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1616 | |

DATE MAILED: 06/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/519,677 | YANAGAWA, AKIRA | |
| | Examiner | Art Unit | |
| | James H. Alstrum-Acevedo | 1616 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *07 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☒ Claim(s) *3* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/7/05;4/7/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

**Claims 1-10 are pending.**

### *Specification*

The abstract is objected, because it should consist of one paragraph only.

> **Abstract of the Disclosure**: See MPEP § 608.01(f). A brief narrative of the disclosure as a whole **in a single paragraph** of 150 words or less commencing on a separate sheet following the claims. In an international application, which has entered the national stage (37 CFR 1.491(b)), the applicant need not submit an abstract commencing on a separate sheet if an abstract was published with the international application under PCT Article 21. The abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO. See MPEP § 1893.03(e).

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim 3 is objected to because of the following informalities: the words "scopolamine (line 6)" and "oxycodone (lines 6-7)"are misspelled, all lacking the letter "e" at the end of said words. Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

**Claims 4 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

Claim 4 is indefinite because it has the terms "oxycodone hydrochloride/hydrocotarnine hydrochloride" in parentheses and it is unclear whether this is a claim limitation or merely serves as an example.

Claim 9 provides for the use of a composition for nasal absorption, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

**Claim 9 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101.** See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

*Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue; and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yanagawa (U.S. Patent No. 5,603,943) ("USPN '943").**

The Examiner has noted that USPN '943 lists Dott Research Laboratory as the assignee, whereas the instant application lists Taiho Pharmaceutical Co., Ltd. as the assignee and therefore USPN '943 qualifies as prior art.

### *Applicant Claims*

Applicant claims (1) a composition for nasal absorption comprising a carrier of calcium carbonate and/or calcium phosphate having an average particle size less than 500 microns an effective dose of an opiate analgesic and (2) a method of treating post surgery or cancer pain comprising intranasally administering said composition.

### *Determination of the Scope and Content of the Prior Art (MPEP §2141.01)*

Yanagawa discloses in claims 1-2, 4, and 9-14:

1. A nasally administrable composition comprising a physiologically active substance having a molecular weight of not more than 40,000 and a physiologically acceptable powdery or crystalline polyvalence metal carrier, wherein a physiologically effective amount of said physiologically active substance is dispersed homogeneously in and adsorbed homogeneously onto said polyvalence metal carrier, and a mean particle size of said polyvalence metal carrier is not more than 250 μm.

2. A nasally administrable composition as claimed in claim 1, wherein said polyvalence metal carrier is divalence metal compound selected from the group consisting of aluminum compound, calcium compound, magnesium compound, silicon compound, iron compound and zinc compound.

4. A nasally administrable composition as claimed in claim 2, wherein said calcium compound is selected from the group consisting of apatite, hydroxyapatite, calcium carbonate, calcium disodium EDTA, calcium chloride, calcium citrate, calcium glycerophosphate, calcium gluconate, calcium silicate, calcium oxide, calcium hydroxide, calcium stearate, calcium phosphate tribasic, calcium lactate, calcium pantothenate, calcium oleate, calcium palmirate, calcium D-pantothenate, calcium alginate, calcium phosphate anhydride, calcium hydrogenphosphate, calcium primary phosphate, calcium acetate, calcium saccharate, calcium sulfate, calcium secondary phosphate, calcium para-aminosalicylate, and bio calcilutite compounds.

9. A nasally administrable composition as claimed in claim 4, wherein said calcium compound is hydroxyapatite, calcium carbonate or calcium lactate.

10. A nasally administrable composition as claimed in claim 5, wherein said magnesium compound is magnesium stearate.

11. A nasally administrable composition as claimed in claim 3, wherein said aluminum compound is aluminum hydroxide.

12. A nasally administrable composition as claimed in claim 1, wherein said polyvalence metal carrier has a mean partice size of not more than 100 μm.

13. A nasally administrable composition as claimed in claim 12, wherein a mean particle size of said polyvalence metal carrier ranges from 30 μm to 60 μm.

14. A nasally administrable composition as claimed in claim 1, wherein the physiologically active substance having a molecular weight of not more than 40,000 is any one of compound selected from the group consisting of physiologically active peptide, hypnotics and sedatives, anti-epileptics,

It is noted that sedatives, as disclosed in claim 14, includes opiates, as is art recognized. The art recognizes that **codeine, hydromorphone, levorphanol, morphine, oxycodone, meperidine, buprenorphine, butorphanol, dezocine, nalbuphine, propoxyphene, meperidine, and pentazocine are sedatives and analgesics** (See the Drug Information Handbook, Lexi-Comp, Inc.: Cleveland, 1994-1995, pp 1066).

***Ascertainment of the Difference Between Scope the Prior Art and the Claims***

***(MPEP §2141.012)***

The prior art lacks the express teaching of specific opioid analgesics. However, opioid analgesics are well-known art recognized compounds (See 1994-1995 Drug Information Handbook).

***Finding of Prima Facie Obviousness Rational and Motivation***
***(MPEP §2142-2143)***

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention that the term sedative in claim 14 of USPN '943 obviously encompasses opiates, because it is well known in the art that many opiates in addition to being analgesics are sedatives too (1994-1995 Drug Information Handbook). Furthermore, it would have been apparent to a skilled artisan that in addition to using an opioid compound as a sedative one could utilize it as an analgesic, because opiates are well known analgesics. A skilled artisan would have been motivated to modify the teachings of '943 to include opiate analgesics because many opiates are both sedatives and analgesics, as evidenced by the table on page 1066 of the 1994-1995 Drug Information Handbook (DIH). Additionally, because the relative sedating/analgesic effect of opiates is known (DIH), a person of ordinary skill in the art would have been able to

select an appropriate opiate or pharmaceutically acceptable salt thereof for use in the carrier compositions disclosed in USPN '943 with a reasonable expectation of success.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

**Claims 1-10 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 4, and 9-14 of U.S. Patent No. 5,603,943 (USPN '943).** Although the conflicting claims are not identical, they are not patentably distinct from each other because they are substantially overlapping in scope and are mutually obvious. Both USPN '943 and the instant application recite nasally administrable compositions comprising an active compound homogenously distributed and attached to a carrier, wherein the carrier is calcium carbonate or calcium phosphate and the carrier/active particles have a size of less than 500 microns (USPN '943 recites particle sizes less than 250 microns in claim 1). It is

also noted that opiates are art recognized analgesics, many of which are also sedatives. Sedatives are recited in claim 14 of USPN '943 as a suitable active agent distributed on/or attached to calcium carbonate and/or calcium phosphate carriers. Therefore, the Examiner concludes that claims 1-10 of the instant application are *prima facie* obvious over claims 1-2, 4, and 9-14 of USPN '943.

### *Conclusion*

**The abstract and claim 3 are objected. Claims 1-10 are rejected. No claims are allowed.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0664. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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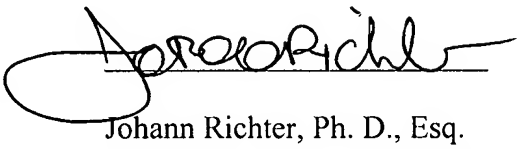

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